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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
LANDSMAN, ROBERT S				
ART UNIT		PAPER NUMBER		
1647				

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/082,221

Applicant(s)

FERGUSON, MARK W.J.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Upon further consideration, the finality of the last Office Action has been withdrawn and prosecution on the merits continues.

### ***1. Formal Matters***

- A. The Amendment dated 12/9/04 has been entered into the record.
- B. Claims 11-17 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Priority***

- A. It appears that Applicants are claiming foreign priority. However, there is no claim of priority to a 371 application in the Filing Receipt, nor have copies of the foreign priority documents been received. Clarification of this is requested.

### ***3. Claim Rejections - 35 USC § 112, first paragraph - enablement***

- A. Claims 11-17 remain rejected for the reasons already of record on pages 2-7 of the Office Action mailed 6/3/04. Applicants have amended the claims to remove reference to any homology less than 95%. However, issues still remain regarding the phrase “a fragment thereof.” Applicants argue that since IL-10 and certain variants were known, it would have been routine to make fragments of IL-10 which have the desired function. This argument has been considered, but is not deemed persuasive. Applicants still have not taught which residues are necessary maintain the functional characteristics of the IL-10. In theory, the protein could be as short as 1 amino acid. Applicants have not provided this type of guidance or working examples.

This rejection could be overcome if, in claim 11, part (ii), after the phrase “a partially modified form of human IL-10” Applicants replaced the phrase “, or a fragment thereof,” with “that differs from human IL-10 by the addition, deletion, or substitution of at least one amino acid and.”

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**4. Claim Rejections - 35 USC § 112, first paragraph – written description**

A. Claims 11-17 remain rejected for the reasons already of record on pages 8-9 of the Office Action mailed 6/3/04. Applicants have amended the claims to remove reference to any homology less than 95%. However, issues still remain regarding the phrase “a fragment thereof.” Applicants argue that since IL-10 and certain variants were known, it would have been routine to make fragments of IL-10 which have the desired function. This argument has been considered, but is not deemed persuasive. Applicants still have not taught which residues are necessary maintain the functional characteristics of the IL-10. In theory, the protein could be as short as 1 amino acid. Applicants have not provided adequate written description as to what changes, other than those taught in the prior art, could be made to human IL-10.

This rejection could be overcome if, in claim 11, part (ii), after the phrase “a partially modified form of human IL-10” Applicants replaced the phrase “, or a fragment thereof,” with “that differs from human IL-10 by the addition, deletion, or substitution of at least one amino acid and.”

**5. Claim Rejections - 35 USC § 112, second paragraph**

A. The rejection of claims 11-17 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants’ arguments and the fact that the phrase “anti-inflammatory healing functionality” is clear to one in the art.

**6. Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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A. Claims 11-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,387,364. Although the conflicting claims are not identical, they are not patentably distinct from each other because The claims of the patent recite methods for promoting wound healing with reduced scarring, as well as treating fibrotic disorders, by administering IL-10 to a person in need of such treatment. The present application recites identical methods except that the claims do not recite "to a subject in need." However, it would have been obvious at the time of the present invention to have administered IL-10 to a person in need of treatment as opposed to a person not in need since this would be a waste of resources and could be potentially dangerous.

***7. Claim Rejections - 35 USC § 102***

A. The rejection of claims 11-17 under 35 USC 102 as being anticipated by Gordon et al. has been withdrawn in view of the fact that the Examiner cannot make a prime facie case that the concentrations of Gordon are sufficient to heal wounds with reduced scarring.

***8. Claim Rejections - 35 USC § 103***

A. The rejection of claims 11-17 under 35 USC 103 as being unpatentable by Gordon et al. has been withdrawn in view of the fact that the Examiner cannot make a prime facie case that the concentrations of Gordon are sufficient to heal wounds with reduced scarring, nor could the Examiner find any references in the art to combine with Gordon to make any rejection under 35 USC 103.

***9. Conclusion***

A. Claims 11-17 would be allowable if amended as seen under 35 USC 112, first paragraph as well as upon the filing of a Terminal Disclaimer.


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***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ROBERT S. LANDSMAN, PH.D.  
PRIMARY EXAMINER

Robert Landsman  
Primary Examiner  
Art Unit 1647